JUN 2 2 2000

K000978

SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR: Biomet Inc.
P.O. Box 587
Airport Industrial Park
Warsaw, Indiana 46581

ESTABLISHMENT REGISTRATION NUMBER: 1825034

DEVICE NAME: Anatomic Total Knee Prosthesis

DEVICE CLASSIFICATION: Knee joint, femorotibial, metal/polymer, semi-constrained, cemented prosthesis – Product code HRY, class II, (21 CFR Part 888.3530)

INTENDED USE: The Anatomic Total Knee Prosthesis is designed to allow replacement of the articulating portions of the knee joint. The indications for use are the same as for any conventional knee prosthesis. These include the relief of pain and restoration of impaired function due to non-inflammatory degenerative joint disease, rheumatoid arthritis, deformities of the knee, and revisions of previously failed knee replacements. The device is for use with bone cement.

DEVICE DESCRIPTION: Three components make up this system, a cobalt-chromium-molybdenum alloy (ASTM F-75) femoral component, an ultra-high molecular weight polyethylene(ASTM F-648) bearing surface molded to a titanium alloy (ASTM F-136) tibial base and stem component, and a polyethylene patella button. The femoral component is available in two sizes in left and right configurations. The anatomic design of the components reconstructs the kinematics of the natural femur. The patellar groove is angled to follow the anatomic axis, providing a natural femoral alignment.

The bearing surface of the tibial component has a knob protruding centrally that rides between the condyles during flexion. Within the polyethylene surface is a titanium strut to help in supporting the polyethylene. The bearing surface is compression molded to the base plate to make a one-piece tibial component.

POTENTIAL RISKS: The potential risks associated with this device are the same as with any joint replacement. These include, but are not limited to the following.

Reaction to bone cement	Blood vessel damage	Bone fracture
Deformity of the joint	Soft tissue imbalance	Infection
Cardiovascular disorders	Delayed wound healing	Hematoma
Fracture of the cement	Metal sensitivity	Dislocation
Implant loosening/migration	Component fracture	Excessive wear
Nerve damage	Pain	

SUBSTANTIAL EQUIVALENCE: The Anatomic Total Knee Prosthesis is substantially equivalent to the following devices.

The Sheehan Total Knee System	Zimmer
The AGC Knee Prosthesis	Biomet Inc.
The AGC Revision Knee Prosthesis	Biomet Inc.
The MCK (Maxim) Knee Prosthesis	Biomet Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 22 2000

Mr. Lonnie Witham
Senior Regulatory Affairs Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46580

Re: K000978
Trade Name: Anatomical Total Knee Prosthesis
Regulatory Class: II
Product Code: JWH
Dated: March 20, 2000
Received: March 27, 2000

Dear Mr. Witham:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number K000978

Device Name: Anatomic Total Knee Prosthesis

Indications for Use:

The indications for use of the Anatomic Total Knee Prosthesis are the same as for any conventional knee joint replacement prosthesis. These indications include the relief of pain and the restoration of impaired function due to non-inflammatory degenerative joint disease, rheumatoid arthritis, deformities of the knee, and revision of previously failed knee replacements. The device is for use with bone cement.

Standard surgical and rehabilitative procedures are indicated with this device

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use V OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Donna R. Bachman
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000978